

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No. 047998/0128

In re patent application of BRODEUR et al.

Serial No.: 08/913,362

Group Art Unit: 1641

Filed: November 3, 1997

Examiner: Graser

For:

PROTEINASE K RESISTANT SURFACE PROTEIN OF NEISSERIA MENINGITIDIS

## **DECLARATION UNDER 37 CFR §1.132**

- I, Bernard R. Brodeur, declare that:
- I am a citizen of Canada, residing at 2401 Maritain, Sillery, Quebec, G1T 1N6. 1.
- I hold the position of Director of the Vaccine Research Unit («Unité de Recherche en 2. Vaccinologie») at the Laval University Research Center («Centre Hospitalier de l'Université Laval»).
- 3. I have assigned my rights to Biochem Pharma Inc., 275 Armand-Frappier Boulevard, Laval, Quebec, Canada H7V 4A7.
- I am a co-inventor named in U.S. application Serial No. 08/913,362 ("the 4. application"). In relation to the application, I have reviewed an Office Action, mailed June 7, 2000, and publications cited there, including an article of Wedege and Froholm, Infection and Immunity 51: 571-78 (1986).
- 5. It is well known art that Coomassie Brilliant Blue stains some proteins strongly but others only slightly, as a function of structural differences between the proteins. More specifically, the intensity of Coomassie blue staining was correlated to the number of lysine, histidine and arginine residues present in the protein (Merril C.R., Gel Staining



Serial No. 09/228,958

techniques, In Guide to protein purification. Methods in Enzymology vol. 182. Ed M.P. Deutscher. 1990, a copy of which is enclosed as exhibit 1). Certain proteins such as histones or acid proteins have been reported to escape staining by Coomassie blue (DM Bollag and SJ Edelstein. 1991. Protein Methods. Wiley-Liss Inc. is enclosed as exhibit 2) Wedege and Froholm appear to describe a 22 kD Neisseria meningitidis protein that does not stain with Coomassie Brilliant Blue. Several research groups (Cannon et al. 1984. Infection and Immunity 43.994-999; Battacharjee et al. 1988. Infec. Immun. 56: 773-778, a copy of which is enclosed as exhibits 3, and 4) reported the existence in the meningococcal outer membrane of a conserved protein with an apparent molecular mass of 20 kDa, called H.8 or lip, which could not be detected by Coomassie blue staining that might correspond to the protein described by Wedege et al.. By contrast, the 22 kD Neisseria meningitidis protein of the application does stain with Coomassie Brilliant Blue. From this difference, a person knowledgeable in this field would infer that the respective proteins of the application and of Wedege/Froholm article are different.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Sept 1, 2000

Signed, Dr Bernard Brodeur, PhD.